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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,439	01/26/2001	Kazuko Matsumoto	TOYAM67.001AUS	8038

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/21/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/771,439

Applicant(s)

MATSUMOTO, KAZUKO

Examiner

Stephanie Zitomer

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### Application status

1. Receipt of the amendment filed January 16, 2002 is acknowledged.
2. Rejections set forth in the previous Office action, paper no. 6, mailed June 28, 2001, have been withdrawn in view of the amendments to the claims except as noted. Applicant's arguments traversing the art rejections have been fully considered but are moot in view of withdrawal of the rejections.

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

### Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The amended recitation "whereby immobilized portions of the immobilized nucleic acids are provided on the nucleic acid-immobilized substrate" is confusing in that (i) it is redundant; and (ii) it is unclear whether only a "portion", the "immobilized portion" of each immobilized single-stranded nucleic acid is immobilized on the substrate or only some of the single stranded nucleic acids are immobilized.

(b) Syntax problems due to the amended phrase "and contained in the sample nucleic acid solution" render the claims confusing. It is suggested to put the "and" at the end of the phrase and move the phrase to the next line up, after the first "nucleic acids".

(c) The recitation "bringing...into contact...to allow hybridization of the immobilized single-stranded nucleic acids..." is not an active method step as it should be but it is simply a statement of future intended use. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter the claims encompass as well as make clear the subject matter from which others would be precluded. *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

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(d) In the second and third indented portions of the claims "hybridized single-stranded nucleic acids" lacks antecedent basis in the first indented portion due to the absence of a positive hybridizing step. See above at (c).

(e) The claims are confusing in the amended recitation, "thereby collecting..." because "collecting" is not a natural or expected sequela of "separating".

(f) The amended recitations at (1) and (2) in the third indented portion of the claims lack proper antecedent basis in the first two indented portions because the second portion specifically requires "collecting the hybridized single-stranded nucleic acids without disassembling the nucleic acid-immobilized substrate (emphasis added) whereas the specification discloses at page 18 that "rubbing off" and "shaving off" remove a portion of the substrate, i.e., of the nucleic acid-immobilized substrate.

(g) The amended recitation at (3) in the third indented portion of the claims lacks proper antecedent basis in the first two indented portions because there is no provision therein for an electroconductive substrate as required at page 19 of the specification.

(h) The amended recitation at (3) in the third indented portion of the claims further lacks proper antecedent basis in the first two indented portions because it is a denaturing step and it is unclear in the second portion of the claims that denatured single-stranded nucleic acids are "separated". In this regard, applicant's clarification at page 3 of the Amendment points out that "the hybridized nucleic acid may be separated either in denatured form or in hybridized form" with reference to pages 18 and 19 of the specification. In turn, it is pointed out that five techniques for separating the hybridized nucleic acids are disclosed at pages 18-19, two of which remove hybridized immobilized nucleic acids with a portion of substrate and three of which are denaturing techniques. It is suggested that the present lack of clarity and antecedent bases in the claims can be corrected by providing separate claims for the two different kinds of techniques.

**Rejection under 35 U.S.C. 102(e): Anticipation**

4. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(e) as being anticipated by the patent to Mills, Jr. et al. (6,150,102) in view of Heller et al. (5,605, 662). Regarding claim 1, Mills, Jr. et al. disclose a method comprising bringing a sample nucleic acid solution into contact with a nucleic acid-immobilized substrate comprising a substrate and single-stranded

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nucleic acids having different nucleotide sequences, said single-stranded nucleic acids being each separately immobilized on the substrate, whereby immobilized portions of the immobilized nucleic acids are provided on the nucleic acid-immobilized substrate to allow hybridization of the immobilized single-stranded nucleic acids and single-stranded nucleic acids complementary to the immobilized single-stranded nucleic acids (column 7, lines 46-62; column 12, lines 28-32) and separating and collecting the hybridized single-stranded nucleic acids on the immobilized portions of the immobilized nucleic acids from the substrate thereby collecting the hybridized single-stranded nucleic acids without disassembling the nucleic acid-immobilized substrate (column 13, lines 16-21; column 25, claim 1). The claimed invention method differs from that of Mills, Jr. wherein the hybridized single-stranded nucleic acids are separated by means of applying an electric potential difference across the immobilized portions. However, Mills, Jr. discloses the teaching of Heller et al. (5,605,662) that hybridized nucleic acids immobilized on an electronic device can be separated by applying a sufficient negative potential (Heller et al., column 20, lines 37-38) (Mills, Jr., column 14, lines 38-41). It would have been obvious and one of ordinary skill in the art at the time the claimed invention was made would have been motivated to apply an electric potential difference across the immobilized portions of the hybridized nucleic acids to separate them from the nucleic acids-immobilized substrate of Mills, Jr. in view of the further statement of Mills, Jr. that "[t]hus, an array of micro-electrodes integrated within, or closely associated with, a substrate supporting an oligomer-storing array of depot sites can be used to create denaturing conditions at selected depots of the array to practice the present invention" (column 14, lines 41-45). It would have been further obvious to the skilled practitioner in the art to apply the electric potential difference across all of the immobilized portions according to preference and experimental parameters.

Regarding the embodiment of claims 3 and 4 wherein the immobilized nucleic acid is DNA the patent teaches that the immobilized nucleic acid is DNA (column 25, claim 2). Regarding the embodiment of claims 5-8 wherein the substrate has a "plate-shape", "plate-shape" is interpreted as a flat surface such as glass or a silicon wafer as disclosed in the Mills, Jr. patent (column 8, lines 12-20; column 10, lines 4-5).

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5. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills, Jr. et al. (6,150,102) as applied to claims 1 and 3-8 above in view of Takenishi et al. (6,017,742). The claimed invention method of claim 2 differs from that of Mills, Jr. et al. wherein the substrate carries a compound having a carbodiimide group. However, Takenishi et al. teach a method of immobilizing nucleic acids on a substrate carrying a carbodiimide group wherein the substrate may be a plate (column 3, lines 52-67; column 11, Example 10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the Takenishi et al. plate carrying a carbodiimide in the method of Mills, Jr. et al. because the skilled practitioner in the art would have been motivated by the routine practice in the art of using carbodiimide chemistry for immobilizing biological molecules on a substrate and by the advantages of ease of handling, reactivity and adhesiveness taught by Takenishi et al. (column 2, lines 39-49; column 3, lines 22-24).

**Prior art of interest**

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Stanley (5,824,477) is cited for teaching a method of denaturing, i.e., separating, hybridized single-stranded nucleic acids on a nucleic acid-immobilized substrate by applying an electric current to the nucleic acids (claim 26).

**Conclusion**

7. **No claim is allowed.**

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.

  
Stephanie Zitomer, Ph.D.

March 15, 2002